

**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: [REDACTED]

*IRB Use Only*

Approval Date: July 18, 2017

Protocol Title: A Phase II Study of Etrinecetan Pegol (NKTR 102) in Patients with Refractory Brain Metastases and Advanced Lung Cancer or Metastatic Breast Cancer (MBC)

Are you participating in any other research studies? \_\_\_\_ Yes \_\_\_\_ No

**PURPOSE OF RESEARCH**

You are invited to participate in a research study for lung and breast cancer that has spread to the brain (brain metastases) using an investigational chemotherapy drug called etirinecetan pegol (NKTR-102). You were selected as a possible participant in this study because your brain metastases are either refractory (grown after prior treatment) or you are not eligible for standard treatment. This research study is being done to see whether NKTR-102 is effective for treating lung and breast cancer with brain metastases.

The use of NKTR-102 in this study is investigational. The word “investigational” means that NKTR-102 is not approved by the Food and Drug Administration (FDA) for this indication. However, the FDA is allowing the use of NKTR-102 as part of this research study.

If you decide to terminate your participation in this study, you should notify [REDACTED]

This research study is looking for 27 people with lung cancer or breast cancer that has spread to the brain. This is a single-center study being conducted at Stanford University.

This study is being paid for by Nektar Therapeutics, a biopharmaceutical company in San Francisco, California. They will be providing the study drug.

**VOLUNTARY PARTICIPATION**

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

**DURATION OF STUDY INVOLVEMENT**

Your time in this study will be determined by how well you respond to the treatment. In other words, your time on this study will be counted in treatment cycles. The number of cycles you receive will be based on the side effects you experience, how well your cancer responds to the study treatment and if the study doctor feels it is in your best interest to continue. You can also withdraw your consent at any time. This study will take approximately 36 months to enroll and treat all 27 patients.

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**PROCEDURES**Before you begin this study:

You must sign this consent form prior to doing any study specific tests or evaluations. You will need to have certain medical examinations, tests, or procedures to find out if you can be in the study. Some may be part of your regular medical care. If you have had some of these exams, tests or procedures done recently (within 21 days), they may not need to be repeated.

The following will be done to see if you are eligible to join the study:

- Medical and cancer history
- A review of all the medications you are currently taking, including all prescription and non-prescription medications (vitamins, herbal supplements, over the counter medications)
- Physical examination and vital signs
- Blood (1 tablespoon) and urine samples will be collected for routine tests to evaluate liver, bone marrow, clotting, metabolic and kidney functions
- If you are a woman capable of having children, your blood will be tested to make sure you are not pregnant
- Brain MRI (Magnetic Resonance Imaging) and Body CT (Computed Tomography)

During Study Treatment:

You will receive study drug NKTR-102 on Day 1 of each cycle. One cycle is 3 weeks, or 21 days, long. You will need to come to the study center on the first day of every cycle during all cycles to receive the dose of study drug NKTR-102. The study drug NKTR-102 will be given through a needle into your vein slowly (intravenous [IV] infusion). This will take about 90 minutes. While you are receiving the study drug, NKTR-102, the study staff will watch you closely for any side effects you may have. If you are experiencing certain side effects, the dose of NKTR-102 may be reduced.

Many of these tests are part of regular cancer care, but may be done more often because you are in the study.

- Physical Exam and vital signs
- Medical history will be reviewed and updated
- Blood (1 tablespoon) will be collected for routine tests to evaluate liver, bone marrow, metabolic and kidney functions. This may be done up to three days before the infusion

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- Review of any side effects you may be experiencing and any medication you are taking
- In the middle of each cycle, the study staff will contact you to review any side effects you may be experiencing
- Brain MRI and body CT will be done every 6 weeks. After 12 weeks, imaging may be done every 9-12 weeks if the study doctor feels it is appropriate
- About 1-2 tablespoons of blood will be collected for genetic tumor markers at Cycle 1, Cycle 2, Cycle 3, Cycle 5 and then each imaging visit

End of Study:

Approximately 30 days after your last dose of NKTR-102, you will be asked to return to a final Study Visit. At this visit, you will have the same procedures performed as at a Treatment Visit (described above), except you will not have the NKTR-102 infusion, MRI or CT scan. If you are not able to come into the clinic for the visit, you may be contacted by phone.

Follow Up:

After the end of study visit, the Study Team will continue to follow you for survival approximately every 3 months, unless you specifically withdraw your consent for this. This may include information from your continued visits to your doctor; review of your medical record; and/or phone calls to you. Collected information may include any subsequent anti-cancer therapy and disease progression.

MRI (Magnetic Resonance Imaging)

MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. The scanning procedure is very much like an X-ray or CT scan. You will be asked to lie on a long narrow couch for a certain amount of time while the machine gathers data. During this time you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling.

Risks:

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room.

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All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator. You should also notify the operator/investigator if you have any tattoos on your body, including eyeliner and other permanent makeup. Tattoos could become warm and irritated during the scan and remain so for several days. If you would prefer not to participate in the MR scan due to the presence of tattoos on your body, please inform a research team member.

If you have had a previous reaction to Gadolinium-based contrast agents or a history of severe allergies, please notify the operator/investigator. If you have kidney problems, please tell the operator. It has been observed that deposits of Gadolinium-based contrast agent (GBCA) remain in the brains of some people who undergo four or more contrast enhanced MRI scans, long after the last administration. It is not yet known whether these Gadolinium deposits are harmful or can lead to adverse health effects. You should talk to the study doctor if you have any questions about the use of GBCAs with MRIs

**IF YOU FEEL DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME.**

A **computed tomography (CT) scan (an “X-ray”)** with or without contrast may be performed according to standard practice. The CT scan will be used to look at the blood flow and the extent and activity of your cancer. This scan is part of your normal medical care. The scan will take about 30 to 60 minutes. You will need to remove all jewelry, piercings, and other metal items. A tourniquet will be applied to your arm or leg to help find a vein, and a contrast agent will be injected into a vein. The entire scan procedure will take about 30 to 60 minutes. You will be asked to lie still on a long narrow bench, or scanner bed, for up to 45 minutes. You will be asked not to move during the scan and to relax and breathe normally. A strap and/or pillows may be placed across your body to prevent movement. You may experience some discomfort or anxiety from being in the confined space. If this bothers you too much, the study team may provide you with a medication to help you stay calm. During the CT scan procedure, the scanner will rotate around you, and make clicking sounds, which is normal. Tell the CT technician immediately if you have any breathing difficulties; sweating; numbness; or heart palpitations.

Women of Childbearing Potential

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not

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participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study.

You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation for at least 6 months after your last dose of NKTR-102. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

If you are a man participating in this study and your partner is able to become pregnant, you and your partner must use adequate contraception while you are participating in the study and for at least 6 months after your last dose of NKTR-102. Your doctor will discuss with you what methods of birth control are considered adequate. You should inform your study doctor if your partner becomes pregnant

**Tissue Sampling for Genetic Testing**

As part of the analysis on your samples, the investigators will do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

The results of the study of your samples from this project will be used for research purposes only, and you will not be told the results of the tests.

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Handling of your Blood Samples for Cancer DNA Testing

Your blood sample for cancer DNA testing will be processed and stored in the laboratory of [REDACTED] Radiation Oncology in the Stanford Cancer Institute.

Your tissues will be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, eg, as part of your routine clinical care, but not for additional research.

Donors of samples do not retain any property rights to the samples.

**PARTICIPANT RESPONSIBILITIES**

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Be sure to tell the study staff all of your medical history, allergies and any drugs or medications you are taking. You should not take any new medicine while you are on this study unless you first check with the study staff.
- Ask questions as you think of them.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or study team if you change your mind about staying in the study.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.

**WITHDRAWAL FROM THE STUDY**

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Protocol Director [REDACTED]

To help you safely finish your participation in the study, the Study Doctors may ask you to come into the clinic for an End of Treatment Visit. The Study Doctors may also ask if you wish to take part in the follow-up portion of the study. If you agree, information

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about your health will continue to be collected as described above in the Follow Up section

The Protocol Director may also withdraw you from the study and the study medication may be stopped, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- If your tumor worsens (tumor progression).
- If you have serious side effects during treatment with Study Drug.
- You become pregnant.
- You need treatment not allowed in the study.
- The study is stopped by the drug manufacturer Nektar Therapeutics; the Stanford Institutional Review Board (the IRB, a group of people who review the research to protect your rights), or by a regulatory agency such as the US Food and Drug Administration (FDA).
- Other administrative reasons.
- Unanticipated circumstances.

**POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES**

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk to the Protocol Director if you have any questions.

You must tell the Study Doctor or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study. Your Study Doctor may give you medications to try to help lessen some of the side effects. All patients in the study will be monitored for side effects.

**Most Common Side Effects of the Study Drug NKTR-102**

Severe and/or life-threatening diarrhea has been seen in 18% of patients who were given the study drug NKTR-102. Severe diarrhea resolved within an average of 14 days.

It is very important to **avoid the use of any laxatives**, and if you feel you need to take a laxative, you must discuss it with your study doctor first. From the first NKTR-102 treatment onwards, you must have anti-diarrhea medicine, loperamide, available at home. It is very important not to take the anti-diarrhea medicine until you actually have experienced loose stools (diarrhea). More details about the medicine and how to take

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(if needed) will be provided to you by your doctor. You must contact your doctor when you have the FIRST loose stool (regardless of how bad it is).

If you develop diarrhea you should drink plenty of fluids to prevent dehydration. In patients receiving NKTR-102, 11% developed severe or life-threatening dehydration from diarrhea. Symptoms of severe dehydration can include lightheadedness and dizziness along with thirst. You may require intravenous fluid replacement. Similarly, diarrhea can affect the electrolyte levels in your blood that may require intravenous replacement.

Low WBC can worsen to the point of being life-threatening or lead to death in the setting of an infection. The low WBC typically resolves on average within 10 days. Any sign of infection in particular a fever (temperature  $\geq 100.4$  °F) should prompt you to call immediately your health care provider. You can also develop a low red blood cell (RBC) count that we define as anemia that may make you feel tired, dizzy, or short of breath. If necessary you may need a blood transfusion and or dose-reduction if your RBC count remains low.

Other common side effects include nausea, fatigue, vomiting, abdominal pain, and decreased appetite. You should contact the Study Doctor if you develop severe nausea, vomiting, or abdominal pain. If you experience nausea or vomiting, you may be anti-nausea medication before future infusions.

Other less common side effects include loss of weight, loss of hair, blurred vision, dizziness, fevers, shortness of breath and headache. Other side effects may also be serious.

Rare but serious side effects that you should call your Study Doctor and seek urgent medical attention for about include:

- Any signs of blood clots, which can be can be serious and life-threatening or fatal. Watch out for: chest pain, shortness of breath and/or swelling in a limb or limbs
- Allergic reaction: itching; skin rash; facial swelling; difficulty breathing (due to swelling in the throat); and/or a sudden drop in blood pressure, possibly with fainting. The sudden drop in blood pressure may lead to shock with loss of consciousness and/or possible seizures, including the possibility of death.

There have also been reports of kidney failure causing death in 3 patients, about 1% of the patients (1 in 100) that were treated with NKTR-102. Kidney failure can occur as a result of severe diarrhea and/or vomiting that leads to loss of fluids from the body known as dehydration. Unless treated immediately, this loss of fluids from the body can be serious and life-threatening and can lead to kidney failure and possibly death. You must contact your doctor immediately if you develop diarrhea or vomiting and you must follow your doctor's instructions regarding the recommended treatment. If required,

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your doctor may order some laboratory tests to see if your kidneys are working normally. There is always a chance that any medical treatment can harm you. In addition to the risks listed above, you may have other side effects associated with the study drug that are not known at this time. You will be told about any important new findings that may affect your decision to remain in the study.

On 17 March 2015, Nektar Therapeutics announced results of the BEACON study, a trial comparing NKTR-102 to Treatment of Physician's Choice ("TPC", any of 7 standard of care anticancer drugs) in women with advanced breast cancer. In a topline analysis of 852 participants from the trial, NKTR-102 provided a 2.1 month improvement in median overall survival (OS) over (12.4 months for participants receiving NKTR-102 compared to 10.3 months for participants receiving TPC). The overall comparison of survival did not show a statistically-significant result comparing the NKTR-102 group to the TPC group.

The incidence of severe toxicities was lower in the NKTR-102 arm (48%) compared to the TPC arm (63%). Common severe toxicities observed with NKTR-102 were diarrhea (9.6%); low white blood cell counts (9.4%) which could lead to infection, low red blood cell counts (4.7%) which could lead to being tired and fatigue (4.5%).

Common severe toxicities observed with TPC were low white blood cell counts (30.5%) which could lead to infection, low red blood cell counts (4.7%) which could lead to being tired, and feeling short of breath (4.4%). Severe nerve pain was seen in 3.7% of participants on TPC versus 0.5% of participants in the NKTR-102 arm. The full press release can be read on <http://www.nektar.com>.

In addition, there are other risks and possible discomforts you might experience from the study procedures, including:

**Blood draws:** A blood draw may cause inflammation of the vein; stinging, discomfort, or pain; bruising; discomfort; redness; burning; or bleeding at the site where the needle is placed to draw the blood. There is a slight chance of infection. You may feel dizzy or you may faint. If you feel faint, you should immediately lie down to avoid falling.

**POTENTIAL BENEFITS**

The study treatment NKTR-102 may or may not help you. It is not possible to tell how your body will react to the study treatment. Information from this study may help other people in the future, including others with lung or breast cancer with brain metastases.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

**ALTERNATIVES**

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You do not have to be in this study to receive treatment for your lung or breast cancer. The Protocol Director will talk to you about other things you can do for you lung or breast cancer, which may include

- Standard treatment
- Other experimental therapy
- No further anti-cancer therapy and comfort care only.

Please talk to your regular doctor about these options. You can continue to get care from your doctor even if you do not take part in this study

**PARTICIPANT'S RIGHTS**

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director. You can also tell any other member of the study staff.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

**ClinicalTrials.gov**

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**CONFIDENTIALITY**

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of NKTR-102; the results will be provided to the drug manufacturer Nektar

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## Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

### What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to examine the safety and effectiveness of NKTR-102 in lung or breast cancer with brain metastases. Your medical information is information about your physical and/or mental health condition. It includes your previous medical records and information created or collected during the study (for example, the results from various tests or examinations) and the medical information that will be collected from you if you participate in this study.

### Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment.

Signing the form is not a condition for receiving any medical care outside the study.

### If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (eg, necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

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[REDACTED]  
875 Blake Wilbur Dr, Room 2220  
Stanford, CA 94305-5826

**What Personal Information Will Be Obtained, Used or Disclosed?**

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to: demographic information (name, address, contact information, gender, date of birth, ethnicity), medical condition, medical history, specific blood and urine tests, physical examination measures, diagnostic and medical procedures (x-rays, MRI, CT scan), and any reports such as radiology and pathology reports.

**Who May Use or Disclose the Information?**

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, [REDACTED] MD, PhD
- Research Staff
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary

**Who May Receive or Use the Information?**

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the US Department of Health and Human Services (DHHS)
- Nektar Therapeutics, or their representatives
- The Food and Drug Administration (FDA) and/or other state or international regulatory authorities

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

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**When will my authorization expire?**

Your authorization for the use and/or disclosure of your health information will end on 31 December 2064 or when the research project ends, whichever is earlier.

**Will access to my medical record be limited during the study?**

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (eg, if included in your official medical record).

\_\_\_\_\_  
Signature of Adult Participant\_\_\_\_\_  
DateParticipant ID:  
[REDACTED]



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### FINANCIAL CONSIDERATIONS

#### Payment

You will not be paid to participate in this research study. There is no reimbursement offered for any expenses related to your participation in this study.

#### Costs

If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. If you would like to review the list of such covered services, supplies, procedures and care, please tell the study representative now or at any time during the study. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the Study Visits.

You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

#### Sponsor

Nektar Therapeutics is providing financial support and investigational drug for this study.

#### Consultative or Financial Relationships

Dr. Seema Nagpal is a paid consultant to Nektar Pharmaceutical, the company sponsoring this study.

### COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for

Participant ID:

**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: [REDACTED]

*IRB Use Only*

Approval Date: July 18, 2017

Protocol Title: A Phase II Study of Etrinecetan Pegol (NKTR 102) in Patients with Refractory Brain Metastases and Advanced Lung Cancer or Metastatic Breast Cancer (MBC)

supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

**CONTACT INFORMATION**

Questions, Concerns, or Complaints or to Report an Injury or Side Effect: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, [REDACTED]. You should also contact him at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at [REDACTED]. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4<sup>th</sup> Floor, Palo Alto, CA 94306.

Appointment or Alternate Contact: If you need to change your appointment, or if you cannot reach the Protocol Director, please contact the study Research Coordinator [REDACTED]

**EXPERIMENTAL SUBJECT'S BILL OF RIGHTS**

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- Be informed of the nature and purpose of the experiment;
- Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- Be given a description of any attendant discomforts and risks reasonably expected;
- Be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- Be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- Be given an opportunity to ask questions concerning the experiment or the procedures involved;

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- Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- Be given a copy of the signed and dated consent form; and
- Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you? Yes No

Signing your name means you agree to be in this study and that you are given a copy of this signed and dated consent form.

\_\_\_\_\_  
Printed Name of Participant\_\_\_\_\_  
Signature of Adult Participant\_\_\_\_\_  
Date\_\_\_\_\_  
Signature of Person Obtaining Consent\_\_\_\_\_  
Date

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short-form foreign language informed consent document.

\_\_\_\_\_  
Signature of witness\_\_\_\_\_  
Date

(eg, staff, translator/interpreter, family member, or other person who speaks both English and the participant's language)

- Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.
- The English consent form (referred to as the "Summary Form" in the regulations):
  - Must be signed by the witness AND the Person Obtaining Consent (POC).
  - The non-English speaking participant/LAR does not sign the English consent.
  - The non-English speaking participant/LAR should not sign the HIPAA participant line
  - If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.

Participant ID: [REDACTED]